

DIESSE DIAGNOSTICA SENESE SpA
53035 Monteriggioni (SIENA) – Italy – Strada dei Laghi, 39
Tel. +39 0577319554 FAX +39 0577319020



Sede Legale e Amministrazione
20144 Milano (Italy) Via A. Solari 19 sc. 6

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HERPES SIMPLEX 2 IgG RECOMBINANT

Code	91029		
LOT.NO 040-B	2023-07	2022-04	

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93029	E8640	MICROPLATE	039	2023-09	1
PF93529	D8640	CONJUGATE	038	2023-07	1
PF93910	1036	NEGATIVE CONTROL	173	2023-11	1
PF93829	B8640	POSITIVE CONTROL	037	2023-10	1
PF91829	C8640	CUT-OFF CONTROL	037	2023-10	1
PF93619	1034	SUBSTRATE-HS	361	2023-07	1
PF30029	1031	DILUENT 3	046	2023-10	1
PF93603	1035	WASHING BUFFER 10x	448-1	2023-10	1
PF93602	1032/RISK0	STOP SOLUTION	214-2	2024-02	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.013	<0,6 Cut Off
CUT-OFF CONTROL	0.462	≥ 0.200
POSITIVE CONTROL	1.259	>1,5 Cut Off
CV%	7%	≤ 15%

The test has been carried out in accordance with the package insert

TESTED BY: Silvia Sardelli

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents

DATE: 27.05.2024

WARNING: POTENTIAL BIOHAZARDOUS MATERIAL!

This kit may contain some reagents made with human serum or plasma. All serum or plasma used has been tested by an FDA approved method and found non-reactive for HIV-1/2, HCV and HBsAg. Because no method can offer complete assurance that HIV-1/2, HCV, HBsAg or other infectious agents are absent, reagents should be handled with maximum attention.



CERTIFICATE OF ANALYSIS

KIT: **HERPES SIMPLEX 2 IgG RECOMBINANT**
 LOT: **040**
 DATE OF TEST: **25/05/2022**

Code 91029
 Code 91183

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE		<i>FOUND</i>	<i>EXPECTED</i>
A) UNIFORMITY BETWEEN PLATES			
	OD450 nm	1.580	
	CV%	6%	<20%
B) UNIFORMITY WITHIN PLATE			
	OD 450nm	1.509	
	CV%	8%	<15%
2. BULK CONTROL date: 18/05/2022			
A) Average OD of Cut Off Control	OD 450 nm	0.487	≥ 0.200
B) Index of Negative and Positive Sera		accepted	According to specification
C) Sensitivity with working calibrators		accepted	According to specification
3. FINAL CONTROL date: 25/05/2022			
A) Blank	OD 450 nm	0.045	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.013	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.462	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	1.259	> 1,5 Cut Off
E) HOMOGENEITY OF CUT-OFF	No.	6	
	OD 450 nm	0.507	
	CV%	7%	≤15%
F) PRECISION OF FILLING PROCESS			

☒ SATISFACTORY ☐ UNSATISFACTORY

FINAL RESULT: **ACCEPTED**

Date: **25.05.2022**

Signed:
 Released: Q.C. Manager